510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA. 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **SUBMISSION DATE**
   October 5, 2011

6. **TRADE NAME(S):**
   Aquilion CXL, TSX-101A/Q

7. **COMMON NAME:**
   Scanner, Computed Tomography, X-ray

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750)

9. **PRODUCT CODE / DESCRIPTION:**
   JAK – Computed tomography X-ray system

10. **PERFORMANCE STANDARD:**
    21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

11. **PREDICATE DEVICE:**
    TSX-101A/H,/I Aquilion 32/64 SP CT System (K080211)

12. **REASON FOR SUBMISSION:**
    Modification of a cleared device

13. DEVICE DESCRIPTION:

The Aquilion CXL is a whole body multi-slice helical CT System, consisting of a gantry, patient couch and console. The system generates up to 128 slices per rotation using a selectable slice-thickness multi-row detector. Additionally, the Aquilion CXL will utilize the new dose-reduction technologies adopted from Aquilion ONE (currently under FDA review), the system substantially reduces patient exposure dose and improves image quality.

14. SUMMARY OF INTENDED USES:

This device is designed to produce cross-sectional images of a human body by reconstruction of x-ray transmission data from the same axial plane taken at different angles. These images have been proven to be clinically useful in the diagnosis of spine and head injuries, intracranial tumors, blood clots in the brain, eye trauma, soft tissue lesions in the extremities, gastro intestinal lesions, abdominal and pelvic malignancies and hepatic metastases. CT is also used to evaluate intestinal obstructions, as intra-abdominal abnormalities and to examine musculoskeletal degeneration. This device employs no intended uses that are not in cleared devices already found in the market place.

15. SUBSTANTIAL EQUIVALENCE:

Toshiba Medical Systems Corporation believes that the Aquilion CXL, TSX-101A/Q CT Scanner is substantially equivalent to TSX-101A/H,/I Aquilion 32/64 SP CT System (K080211).

New feature	
Maximum number of slices	Changed from 64 to 128
Application of AIDR algorithm	Not available on previous version
Computer system is updated	Faster reconstruction Additional data storage
Addition of SureXtension	Previously cleared via K093891
Availability of ColonView software	Cleared via k090220
Table weight is extended to 300kg (660lbs.)	Previous weight was 450lbs.
Active collimation to reduce penumbra effect during helical scanning.	Not available on predicate

16. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the

applicable parts of the IEC60601-1 standards and its collateral standards. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via an initial report.

17. SUMMARY OF TESTING:

Testing was conducted utilizing phantoms and accepted image quality metrics. The results of this testing is contained in the user information for the device.

18. CONCLUSION

The Aquilion CXL, TSX-101A/Q CT Scanner complies with the same or equivalent standards and has the same intended use as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

APR 10 2012

Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K112989
Trade/Device Name: Aquilion CXL, TSX-101A/Q
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 12, 2012
Received: March 14, 2012

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Aquilion CXL, TSX-101A/Q

Indications for Use:

Acquisition and display of axial x-ray images of the whole body to include the head.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number _____

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112989